

**REMARKS****Pending claims**

Claim 1 has been amended to more clearly point out and distinctly claim the invention. Claims 2-3 have been canceled through this Amendment. These amendments do not contain new matter and are fully supported by the specification. After these amendments are entered, fourteen (14) Claims (claims 1 and 4-17) are pending.

**Claim Rejections Under 35 USC 112**

Claims 1-13 and 17 were rejected under the 35 U.S.C. §112, first paragraph. The rejection over these claims is respectfully traversed for the following reasons.

Applicants respectfully submit that although the term " polyionic material which is not covalently attached to the surface of the article" does not appear exactly in the specification, the exact term needs not be used in *haec verba* to satisfy the written description requirement of the first paragraph of 35 U.S.C. 112 (*Eiselstein v. Frank*, 52 F.3d 1035, 1038, 34 USPQ2d 1467, 1470 (Fed. Cir. 1995); *In re Wertheim* 541 F.2d 257, 265, 191 USPQ 90, 98 (CCPA 1976). Moreover, in accordance with 37 CFR 1.121(e), substantial correspondence between the language of the claims and the language of the specification.

Applicants respectfully submit that there is clear support or antecedent basis in the specification for the phrase "polyionic material which is not covalently attached to the surface of the article". For example, on page 45, the first complete paragraph, Applicants states:

According to the above-mentioned methods, substrate materials are obtained that comprise one or more tie layers of polyelectrolytes adsorbed onto and/or heteropolarly bound on the surface. Due to this modification, the surface is provided with functional groups such as, for example, carboxy, sulfone, sulfato, phosphono or phosphato groups or primary, secondary or tertiary amine groups. It is these functional groups that may be further reacted with various agents to form the surface-modified substrates of the present invention.

Such statement (i.e., one or more tie layers of polyelectrolytes adsorbed onto and/or heteropolarly bound on the surface) shown substantial correspondence between the language of the claims and the language of the specification. There are other exemplary statements which can be found in the specification, for example, such as a material to be coated, prior to coating, "does not contain any appropriate reactive groups" (page 18, the third paragraph) which clearly indicate no chemical reaction between the material to be coated and a polyionic material as coating material; the substrate material "entraps" part or all of the initial layer of polycationic or polyanionic material (Page 44, the second paragraph); and teachings in the Examples in the specification and incorporated co-pending application (Patent Application No. 09/774,942). It is well known that any

appropriate reactive groups on a material to be coated must be present to ensure a covalent attachment of the polyionic material (coating material) to the material to be coated. The term "entrap" and the teachings of examples indicate non-covalent attachment. The teachings in the incorporated copending application further illustrate that a layer-by-layer deposition technique, similar to the present invention in forming the polyelectrolyte layer on a substrate, is used to form a transferable coating on the molding surface of a mold before forming a lens therein and then the coating is transferred to a contact lens formed within the mold. Clearly, the transferable coating on the molding surface of the mold is not covalently attached to the molding surface of the mold.

In sum, Applicants respectfully submit that the claim limitation is fully supported by the originally-filed specification. Applicants respectfully request withdrawal of the rejection under the 35 U.S.C. §112, first paragraph.

#### **Rejections Under 35 USC 102(b)**

Claims 1-2, 5-6, and 12-13 were rejected under 35 USC 102(b) as being anticipated by Nakagawa et al. (US Pat. 5,409,731). Claims 2-3 have been canceled through this Amendment and therefore this rejection over claims 2-3 is moot in view of this Amendment. The rejection over claims 1, 5-6 and 12-13 is respectfully traversed for the following reasons.

Applicants respectfully submit that the cited reference (Nakagawa et al.) does not disclose not suggest anything about covalently linking a layer of an active agent to said reactive sites, wherein the active agent is an anti-microbial agent, a polymeric initiator, a polymer, or a hydrophilic polymer, provided each of the polymer and hydrophilic polymer is different from any one of the first polyionic material and the second polyionic material. Therefore, Applicants submit that the claimed invention as currently claimed is not anticipated by Nakagawa, since the cited reference does not include every elements of the present invention as currently claimed. Applicants respectfully request withdrawal of the 35 U.S.C. §102(b) rejection.

Claims 1, 3-9, 12-13 and 17 were rejected under 35 USC 102(b) as being anticipated by Sheu et al. (US Pat. 5,807,636). Claim 3 has been canceled through this Amendment and therefore this rejection over claim 3 is moot in view of this Amendment. The rejection over claims 1, 4-9, 12-13 and 17 is respectfully traversed for the following reasons.

Applicants respectfully submit that the cited reference (Sheu et al.) does not disclose not suggest anything about covalently linking a layer of an active agent to said reactive sites, wherein the active agent is an anti-microbial agent, a polymeric initiator, a polymer, or a hydrophilic polymer, provided each of the polymer and hydrophilic polymer is different from any one of the first polyionic material and the second polyionic material. Therefore, Applicants submit that the claimed invention as currently claimed is not anticipated by Sheu et al., since the cited reference does not include

every elements of the present invention as currently claimed. Applicants respectfully request withdrawal of the 35 U.S.C. §102(b) rejection.

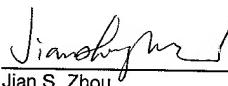
**Rejections Under 35 USC 103(a)**

Claims 10-11 were rejected under 35 USC 103(a) as being unpatentable over Sheu et al. (US Pat. 5,409,731). The rejection over claims 10-11 is respectfully traversed for the following reasons.

As discussed above, Sheu et al.) does not disclose not suggest anything about covalently linking a layer of an active agent to said reactive sites, wherein the active agent is an anti-microbial agent, a polymeric initiator, a polymer, or a hydrophilic polymer, provided each of the polymer and hydrophilic polymer is different from any one of the first polyionic material and the second polyionic material. Therefore, Applicants submit that Sheu does not provide any motivation to a person skilled in the art to make necessary changes to its disclosure to arrive at the present invention, the claimed invention as currently claimed is patentable over Sheu et al.. Applicants respectfully request withdrawal of the 35 U.S.C. §103(a) rejection.

Should the Examiner believe that a discussion with Applicants' representative would further the prosecution of this application, the Examiner is respectfully invited to contact the undersigned. Please address all correspondence to Thomas Hoxie, Novartis Corporation, Corporate Intellectual Property, One Health Plaza, Bldg. 430, East Hanover, NJ 07936-1080. The Commissioner is hereby authorized to charge any other fees which may be required under 37 C.F.R. §§1.16 and 1.17, or credit any overpayment, to Deposit Account No. 19-0134.

Respectfully submitted,

  
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